

CDS CONNECT Maintenance and Update

FINAL REPORT (Year 5 of CDS Connect)





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CDS Connect Maintenance and Update

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- Clinical Decision Support (CDS) Connect Work Group members
- CDS Connect Subcontractor Danny Van Leeuwen
- MITRE CDS Connect Project Team
- Health Level Seven, HL7[®], and FHIR[®]

EXECUTIVE SUMMARY

Healthcare is undergoing a digital revolution that will lead to innovations in using technology and data to impact care. As part of the Agency for Healthcare Research and Quality's (AHRQ's) clinical decision support (CDS) initiative, the CDS Connect project was launched in 2016 to put patient-centered outcomes research (PCOR) findings into practice. CDS Connect provides a web-based public platform for integrating evidence-based care more rapidly into clinical practice.

The fifth year of the CDS Connect project¹ focused on system maintenance and updates to ensure that the tools remained shareable, standards-based, and publicly available. The team also focused on ensuring that the project's activities and work product accurately reflect the needs of the community—addressing the perspectives of patients and caregivers as well as the needs of clinicians and content developers. This annual report organizes the project's year-long accomplishments into four task areas: Task Management, Trust Framework, Standards Conformance, and Outreach.

Task Management (manage project resources; Section 2)

New staff with development expertise joined the CDS Connect project team (hereafter "the team") to promote the adoption of standards and implementation of CDS Connect's offerings.

Trust Framework (prioritize activities based on promotion of trust; Section 3)

The team engaged with end users and other stakeholders to identify and prioritize updates. This activity resulted in a framework focused on two primary "must have" themes and one secondary "should have" theme for CDS Connect updates.

Two primary themes were "must have"—

- 1. **Enforce Standards Compliance (CDS Artifacts):** Update CDS artifacts already in the Repository to ensure compliance with applicable standards.
- 2. **Expand the Use of Existing CDS Artifacts:** Improve usability and update the Repository to support expanded use of existing CDS artifacts.

Another secondary theme was differentiated from the others as "should have" —

3. **Increase Trust:** Implement recommendations from the Trust Framework Work Group (WG).

¹ The CDS Connect Maintenance and Update task order is in its second year, while the Health Federally Funded Research and Development Center's (FFRDC) overall support to AHRQ for the CDS Connect project is in Year 5, as referenced throughout this Final Report.

Standards Conformance (ensure that tools adhere to standards and are innovative; Sections 4-7)

CDS Connect tools and artifacts are more likely to be used if they adhere to existing, widely accepted standards and if they include useful innovations for end users. During this period of maintenance and update, the team introduced the following improvements based on the selected themes in Trust Framework task:

- Implemented a process to review and update (where needed) all CDS artifacts in the CDS Connect Repository.
- Updated CDS Connect project artifacts to use the Fast Healthcare Interoperability Resources (FHIR®) Release 4 (R4) data model and follow best practices for Clinical Quality Language (CQL) development.
- Applied Clinical Practice Guidelines (CPG)-on-FHIR® to the Repository to ease their implementation by the CDS community.
- Upgraded the CDS Connect Repository to Drupal 9 for ongoing vendor support.
- Updated and enhanced CDS Application Programming Interface (API) to facilitate access to integrate tools with CDS Connect.
- Upgraded open-source software offerings to align more closely with CQL 1.5.
- Continued the "Lessons Learned" series for the WG, a community of more than 150 CDS members who provide diverse perspectives and help the team identify and prioritize key features and capabilities for CDS Connect).

Outreach (engage with the CDS community; Section 8)

Engaging with the CDS community through various channels promotes adoption of CDS Connect and increases use of the resources. During Year 5, the team continued to adapt to varied engagement formats, innovated its outreach based on limitations posed by the COVID-19 pandemic, and sought diverse outlets to interact with the CDS community. The team engaged with the CDS community in the following ways:

- 1. Participated in four virtual conferences throughout the year, with a focus on practical engagements that directly impact CDS Connect (e.g., immediate use or improvement).
- 2. Expanded its practices to track visit and download metrics across CDS Connect tools.
- 3. Pursued a collective effort to encourage patient partnering in CDS development and implementation (including site updates, WG discussions, and panel).
- 4. Delivered periodic updates to the CDS community through opt-in email notification.

These accomplishments during Year 5—particularly in the areas of system improvements and diversified stakeholder feedback—will enable the team to further its mission success throughout the next period of performance.

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1. INTRODUCTION

As the lead Federal agency charged with improving the quality and safety of America's healthcare system, The Agency for Healthcare Research and Quality (AHRQ) develops the knowledge, tools, and data needed by researchers and clinicians to advance safe, high-quality, and patient-centered care.

To support the evolution of health information technology (IT), AHRQ's Digital Healthcare Research Program funds research to create actionable findings and supports the implementation of those findings as part of cutting-edge clinical practice.

AHRQ helps clinicians and their teams advance a continuous stream of research findings, clinical practice guidelines, and best practices into real-world clinical care through technical products such as clinical decision support (CDS).

The CDS Connect project plays an essential part in AHRQ's patient-centered outcomes research (PCOR) CDS Initiative (as shown in Figure 1). Starting its work in 2016, CDS Connect has become a publicly available infrastructure for sharing interoperable, standards-based CDS.

Stakeholders rely on CDS Connect for its interoperable tools and resources, and they expect the content will adhere to clinical and technical standards. The team made key updates to CDS Connect's underlying technologies and knowledge resources to ensure the system is well maintained and innovative. These updates require specialized testing protocols and intimate knowledge of resources developed by



the CDS Connect project. The team's work in Year 5 executed on these requirements.

The resources available on the CDS Connect platform include—

- <u>Authoring Tool</u>: A tool for developing open-source software for building CDS artifacts.
- <u>Repository</u>: A platform for managing and sharing CDS artifacts, including artifacts developed by The MITRE Corporation (MITRE) and others (e.g., Centers for Disease Control and Prevention [CDC]; Veterans Health Administration).
- <u>Prototype Tools</u>: Tools for testing and integrating CDS into health systems.
- Work Group (WG): A group of CDS community members who provide diverse perspectives in identifying and prioritizing key features and capabilities for CDS Connect.
- Pilots: Proof-of-concept demonstrations based on CDS artifact use cases and testing in live clinical and/or production settings (pilot reports are available).



Figure 1. AHRQ's PCOR CDS Initiative

The first 3 years of the project focused on initial development and proof-of-concept activities. CDS Connect began its next phase of activities in its fourth and fifth years by innovating the resources included in the platform, updating components based on current standards, and building awareness and use of its capabilities by the CDS community at large. Final reports from prior project years are available on CDS Connect. Overall, CDS Connect continues toward recognition as a national hub for standards-based CDS development and implementation.

1.1 CDS Connect Project Tasks

During Year 5, the team focused on four task areas:

 Task Management (Section 2): Ensure effective project operations, including

- staffing, budgeting, invoicing, delivery, quality assurance, and related activities.
- Trust Framework (Section 3): Build on the values set forth in the 2018 Patient-Centered CDS Learning Network white paper² by prioritizing enhancements to CDS Connect based on identified themes and attributes.
- Standards Conformance (Sections 4-7): Maintain and update CDS Connect to meet stakeholder needs and adhere to industry CDS standards.
- Outreach (Section 8): Learn from stakeholders about how to improve CDS Connect for their benefit by conducting meetings, demonstrations, and presentations at conferences, as well as participating in WG meetings and other activities.

² Richardson, J.E., Middleton, B., Platt, J.E., and Blumenfeld, B.H. (2020). Recommendations for Building and Maintaining Trust in Clinical Decision Support Knowledge Artifacts. Learning Health Systems. Available: https://onlinelibrary.wiley.com/doi/full/10.1002/lrh2.10208.



1.2 CDS Connect Year 5 Milestones and Accomplishments

MITRE achieved the following key milestones and accomplishments in Year 5, spanning the entire CDS Connect platform:

Repository

- Continued development and deployment of Clinical Practice Guidelines (CPG)-on-Fast Healthcare Interoperability Resources (FHIR)-based artifact data model in the Repository.
- Completed the Drupal 9 upgrade to maintain support and adopt best practices.

- Simplified development and deployment process.
- Improved user account signup process.
- Expanded end-user capabilities.

Website

- Updated sign-on options for interacting with CDS Connect tools.
- Revised Frequently Asked Questions (FAQs) with current guidance.
- Updated site content to encourage interaction and further recognize the role of patients/ caregivers in CDS Connect.

Authoring Tool

- Achieved alignment with Clinical Quality Language (CQL) 1.5 Mixed Normative/Trial Use specification.
- Added capability to build CQL queries with multiple criteria.
- Expanded external CQL support to allow invoking functions with arguments.
- Extended recommendations to included associated links.
- Updated Values Set Authority
 Center (VSAC) integration to use
 Unified Medical Language System
 (UMLS) application programming
 interface (API) keys and FHIR
 Release 4 (R4) endpoint.
- Implemented usability enhancements (e.g., sort and duplicate CDS artifacts, summary view, tab indicators).
- Improved code base to simplify maintenance and support reuse of CDS Authoring Tool components.

Prototype Tools

- Updated CQL Services, CQL Testing Framework, and Pain Management Summary to support FHIR 4.0.1, CQL 1.5, and UMLS API keys.
- Revised CQL Services to support querying FHIR servers and to allow user-configurable prefetch templates.

CDS Artifacts

- Enhanced review and update guidance.
- Updated CQL logic to use FHIR R4 data model and align with CQL
 1.5 as well as to reflect evidence updates where applicable.
- Revised metadata and Implementation Guides (IG) to reflect recent changes.

WG

- Solicited presenters to share lessons learned using CDS Connect
- Delivered two-part discussion on patient partnering that led to the launch of a Patient Partnering Panel.

Outreach

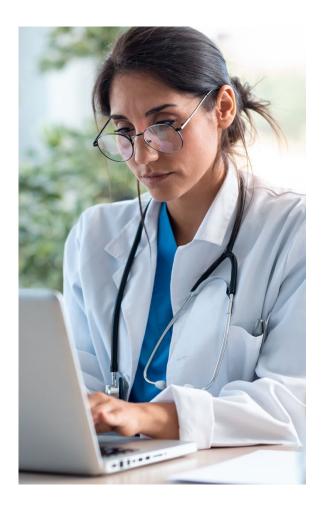
- Expanded its practices to track visit and download metrics across
 CDS Connect tools to inform prioritization and outreach activities.
- Conducted Patient Partnering Panel to support ongoing development of resource materials for CDS Connect.
- Engaged in small-venue outreach activities to encourage use of CDS Connect tools.

2. TASK MANAGEMENT

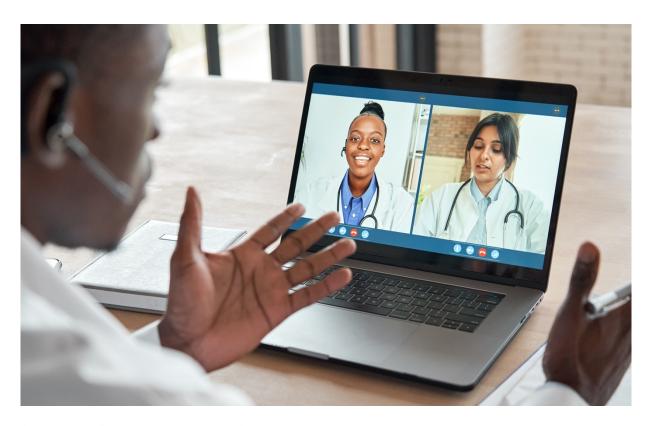
The CDS Connect project team consists of a Project Leader, Deputy Project Leader, Technical Lead, Deputy Technical Lead, Clinical Lead, and Task Leads. The team also continued working with a patient/caregiver activist, Danny van Leeuwen of HealthHats, who provides a unique perspective in the continued development of CDS Connect.

In addition, new staff with expertise in code development and patient partnering joined the team to expand the use of standards in CDS Connect's resources, as well as to increase implementation of available CDS artifacts by the community. The expanded team achieved faster development cycles (e.g., additional CDS Authoring Tool functionality, application CPG-on-FHIR standards to the Repository, and updated guidance for maintaining CDS artifacts).

The team completed 24 2-week sprints, or development cycles, throughout the project year. In addition, the team met regularly to consider, select, develop, test, and implement ideas to maintain and enhance CDS Connect.



Among these ideas were identifying and pursuing priorities in patient partnering and engaging in new events like the HL7 FHIR Connectathon 27. The team also regularly monitored relevant environmental factors (e.g., the potential influence of bias in CDS) to maintain situational awareness and flag potential impacts on the CDS community.



3. TRUST FRAMEWORK

In 2018, the Patient-Centered Clinical Decision Support Learning Network (PCCDS-LN) produced a white paper entitled Recommendations for Building and Maintaining Trust in Clinical Decision Support Knowledge Artifacts.

The recommendations in this white paper included a "Trust Framework" for supporting a trustworthy, knowledge-sharing CDS platform such as CDS Connect. Although CDS Connect has already incorporated several of those recommendations, many of the white paper's recommendations had not yet been implemented (e.g., searching CDS artifacts by knowledge level).

During Year 5, the team continued with improvements to CDS Connect to increase trust in the CDS ecosystem in accordance with the Trust Framework recommendations. The team followed the approach developed

in Year 4 to prioritize the updates to CDS Connect (for additional details on the approach, see the Year 4 report). Guided by the approach developed in Year 4, the team solicited feedback during the October 2020 CDS Connect WG meeting on the themes and trust attributes members believed should be the focus for the current project year.

The team identified two primary "must-have" themes for CDS Connect maintenance and update activities to increase trust in the CDS ecosystem—

- Enforce Standards Compliance (CDS Artifacts): Updated CDS artifacts already in the Repository to ensure compliance with applicable standards.
- Expand the Use of Existing CDS
 Artifacts: Improve usability
 and update the Repository to

support expanded use of existing CDS artifacts.

A third theme was differentiated from the others as "should-have"—

 Increased Trust: Implementing recommendations from the Trust Framework WG.

These themes bounded the scope of priorities for CDS Connect during Year 5 and guided sprint planning and Agile decision making during this project year. Ultimately, the team used the rubric to assess 185 potential updates to CDS Connect. The specific prioritized enhancements included, but were not limited to—

- Update CDS artifacts developed by CDS Connect to use FHIR R4 and CQL 1.5.
- Support CQL 1.5 in CDS Authoring Tool export, external CQL, and testing.
- Support CQL 1.5 in CDS Connect Prototype Tools (CQL Services & CQL Testing).
- Enhance support of CPG-on-FHIR constructs in the CDS Authoring Tool.
- Perform FHIR server callbacks in CQL Services CDS Hooks implementation.
- Expand site redesign to include ease of CDS artifact search by knowledge type, new pages for dissemination and implementation.
- Expand CDS artifact discovery features like sorting searching.
- Pilot additional features to promote use like badges and invitations.
- Enable free-text search in attachments and synonyms.



- Improve maintainability, reusability, and efficiency of CDS Authoring Tool source code.
- Switch to the National Library of Medicine's (NLM) API key authentication in CDS Authoring Tool and Prototype Tools.
- Expand account features to include histories of information viewed.
- Provide better options for showing past versions of CDS artifacts.

As of the writing of this report, the team completed 70 percent (77 of 110) high-priority "must-have" tasks and 86 percent (144 of 167) of the lower-priority "should-have" tasks, as well as ad hoc items from the backlog of candidate enhancements. The team selected ad hoc items based on late-breaking project needs (e.g., updating website content) and staff availability.

The team's efforts in this area produced several positive outcomes. The team also realized the benefits stemming from Year 4 accomplishments (e.g., listing priorities for rapid prioritization throughout the year, avoiding lags between completion of updates and selection of new updates, engaging CDS community), with the additional advantage of being able to reduce resources needed for the prioritization process. The prioritization process was faster and completed with less effort, which resulted in more resources being available for the selection and implementation of additional priorities. Lastly, when the opportunity to add resources to the project at mid-year presented itself, the team was able to quickly define what priorities constituted an achievable scope within the remaining project year. The most highly prioritized CDS Authoring Tool enhancements were selected, including:

- Implement a query builder to allow for more robust CQL queries.
 - Details: Investigate and implement an approach that allows authors to specify CQL queries with flexible criteria using data-type specific properties and comparators.
 - Impact: Queries are one of the most important and powerful features of CQL; allowing authors more control over specific queries provides greater flexibility and expressiveness, decreasing the need for authors to resort to externally authored CQL.
- Provide additional built-in element expressions.
 - Details: Supplement the existing set of element expressions with additional user-requested expressions (such as "First")

- and other expressions deemed useful (such as "Average Observation Value").
- Impact: New expressions provide an easy mechanism for users to express logical constructs that previously were not supported by the CDS Authoring Tool.
- Extend support for external CQL functions.
 - Details: Allow authors to build elements based on functions that declare arguments (if the argument types are supported).
 - Impact: Currently, authors can build elements based on no-argument functions or can use multi-argument functions as expressions (where supported). Standalone multiargument functions provide additional flexibility and opportunities for reuse.
- Improve usability based on user feedback and MedStar report recommendations.
 - Details: Improve usability
 in several key areas, including
 CDS artifact management
 (e.g., supporting duplication
 and sorting of CDS artifacts),
 CDS artifact editing
 (e.g., improving intra-artifact
 linking and controls), and CDS
 artifact review (e.g., providing
 summary views and contextual
 indicators).
 - Impact: These usability improvements allow authors to efficiently manage and build their CDS artifacts, potentially resulting in increased user satisfaction

and productivity. These enhancements will ultimately lead to the creation of a larger number of artifacts that will be of higher quality.

4. STANDARDS CONFORMANCE: REPOSITORY

The CDS Connect Repository was the platform's first prototype tool. The Repository hosts structured, interoperable CDS expressions—known as CDS artifacts—that support clinician and patient decision making. The CDS artifacts on the Repository include contributions developed by the team and by trusted third parties. The goal of the Repository is to demonstrate how to more rapidly incorporate evidence-based research into clinical practice through interoperable CDS.

In Year 1 of the development project, the team developed and delivered initial (alpha) and second (beta) versions of the Repository to AHRQ. For more information on Year 1, please see the final report from that year.

Year 2 saw the release of the third (production) version of the Repository, which was the first version publicly accessible on the Internet. For more information on Year 2, please see the <u>final report</u> from that year.

In Year 3 of the project, the team made enhancements to the production version of the Repository. The <u>final report</u> from that year provides more information.

Year 4 began a new phase that emphasizes long-term maintenance and sustainability of the Repository. During Year 4, the team updated and enhanced the Repository to better align with the most recent CDS-

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related standards. The enhancements improved the user experience for Repository contributors and consumers.

Year 5 continued the focus on making the Repository a maintainable tool with a focus on the user experience. A sizeable percentage of the team's effort involved revising the CDS artifact data model to better align with standards-based data elements, as well as updating the tooling and component dependencies.

4.1 CDS Artifact Schema Update

Since Year 1 of the project, there have been advances in the healthcare IT standards that can be used to describe CDS. In 2020, the first version of the FHIR Clinical Guidelines (also known as the CPG-on-FHIR) IG was released as a standard for trial use (STU). The CPG-on-FHIR was created as part of the CDC's Adapting Clinical Guidelines for the Digital Age initiative. Its purpose is to support "the development of standards-based computable representations of the content of clinical care guidelines" (http://build.fhir.org/ig/HL7/cqf-recommendations/index.html#intro).

Through coordination with the CDS Connect WG and CDS community during Year 4, the team determined that CDS Connect should align its tools with CPG-on-FHIR, where feasible.

At the beginning of Year 4, the team compared CDS Connect's CDS artifact schema with the metadata defined in the CPG-on-FHIR IG (which builds from the FHIR Clinical Reasoning Module). The team documented many alignments and similarities, along with opportunities for harmonization.

The team drafted a proposal to align the schema for the CDS artifacts posted on CDS Connect with CPG-on-FHIR. The CDS Connect WG reviewed that proposal; in addition, external feedback on the proposal was incorporated into a detailed design blueprint, or "mockup," as shown in Figure 2. The goal of this design is to make it easier for users to contribute and consume CDS artifacts on the Repository.

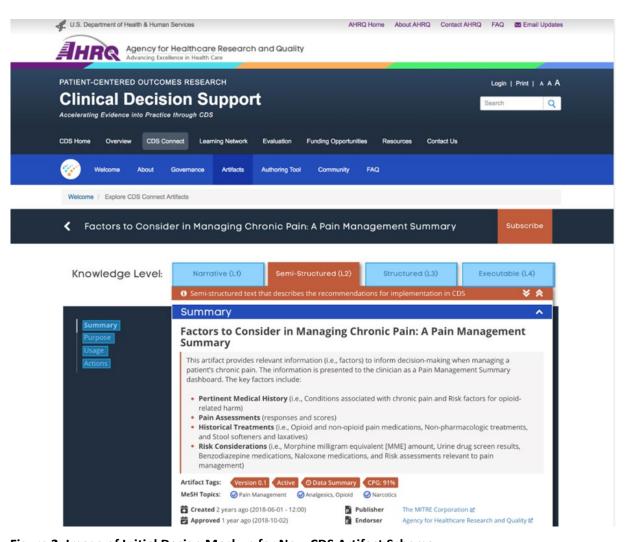


Figure 2. Image of Initial Design Mockup for New CDS Artifact Schema

The initial prototyping in Year 4 of the CPG-on-FHIR-based CDS artifact schema led to focus on determining the best approach, based on user feedback, about how to incorporate elements from multiple knowledge levels into a Repository CDS artifact. The first pass included multiple CDS artifacts, each at a particular knowledge level, all joined together under the concept of a CDS artifact collection. However, after feedback from a WG meeting, the design was modified to instead have a single primary CDS artifact that optionally contained data elements from multiple knowledge levels.

In Year 5, the CPG-on-FHIR data storage and presentation layers were more fully developed. The backend definition of all the fields has been simplified and declaratively structured in a single file. All the fields are grouped by whether they are common to CDS artifacts across knowledge levels or if they are specific to a single knowledge level. Then for each field, the definition includes characteristics such as the title or caption, the description (used for tooltips), the data type, whether it is an array of values, whether it is a reference to other objects in the system, and whether it is a file attachment.

The team performed multiple rounds of internal alpha testing to assist in the iterative development. These alpha testing cycles included users who were not experienced repository developers.

The new CDS Artifact data model now allows a single CDS artifact to contain data elements from multiple knowledge levels. For example, a CDS artifact could be designated as a Level 3: Structured CDS



artifact, but it may now contain elements of a Level 4: Executable CDS artifact.

One key aspect of the new display of artifacts is a CPG completeness score and the progress bar showing the percentage of required elements that have been filled out. This progress bar will be adjusted based on the knowledge level of the artifact—a level 2 artifact will not have level 3 and level four elements included in the calculation.

4.2 CPG-on-FHIR API and Conversion

Additionally, modifications to update the CDS API were started to support create, read, update, delete, and list actions for the CDS Artifact v2 data model. This will support the conversion legacy CDS artifacts (v1) into v2 CPG-on-FHIR CDS artifacts.

The conversion script will list the subset of legacy CDS artifacts to be converted, iterate over each one, convert the current CDS artifact from v1 to v2 (via logic in the conversion script itself that handles mapping and transforming fields), and finally use the CDS API v2 endpoints to create the v2 CDS Artifact objects.

4.3 Simplified Development and Deployment Process

Previously, the team used two separate parallel git repositories to manage development and deployment. The primary development repository was on internal gitlab and was designed to have the ability to install a clean repository from scratch. Then any changes had to be manually copied over to the deployment git repository, which did not have common git history. This approach meant edits had to be separately identified and applied to this second repository.

The development team has moved to using the deployment git repository as the common repository for both development and deployment. These changes make it easier to deploy new features, develop fixes for identified problems, and pull in patches. This approach also helped the team prepare for the move from Acquia Dev Desktop to Acquia Cloud IDE.

4.4 Drupal 9 Upgrade

The team performed a major upgrade of the Drupal from 8.9 to 9.2 in the development environment and is preparing the transition plan for upgrading the production environment.

Drupal is the content management system that underlies the CDS Connect Repository and is the basis for the customization and integration that the Repository team has developed.

Drupal 8.x is reaching end-of-life status and will no longer receive patches after November 2021. This prompted AHRQ to develop plans with MITRE to upgrade CDS Connect Repository to Drupal 9.x several months in advance.

Drupal 9.0 is based on the same code as Drupal 8.9, with deprecated APIs removed. Drupal 9.1 and 9.2 have added new capabilities and enhancements.

This meant that the conversion from 8.x to 9.x was largely an in-place upgrade without the need to reimplement the entire Repository system. This version was a vast improvement on the Drupal 8 upgrade, where many Drupal 8 projects in the community required extensive redesign, rewiring, and thorough testing.

During the upgrade process, several nolonger-required dependencies were removed. Some components that were infrequently updated were also removed or replaced, which helps improve the security posture of the repository.

4.5 Usability Improvements

Several usability improvements were made during Year 5. This included making navigation and interacting with CDS artifacts easier. One such change was the simplification of terminology used in the menu structure (e.g., changing "Artifacts" to "Repository" in the menu, based on stakeholder feedback).

A user guide is also being revised and deployed as online help. The initial content, drafted as a Word document, is being transferred into a Drupal-managed content format via the Drupal Books module. This approach will allow the evolving help material to be managed like artifacts and CDS Connect website content are managed, through the Drupal content management system. Using Drupal-managed content, instead of posting a single PDF guide, will support creating hyperlinks from various parts of CDS Connect to the pertinent subsections within the help guide.

The Reports page was also updated to simplify and speed up the process of adding and maintaining reports. Previously, the Reports section was maintained as a single hardcoded block of HTML. The Repository team changed this to manage the report content as a new Drupal content type, in the manner WG records are managed. Now, when a new report is added, a new reports object is created in the management system and the appropriate fields are populated.

The artifact discovery feature on the Repository page was improved in several ways. Enhancements included the addition of an advanced search by knowledge level feature, displaying an always expanded search field, and adding a welcome message encouraging site visitors to register for a CDS Connect account.

Updates were made throughout the year to the Frequently Asked Questions (FAQ) page. These updates and new entries encouraged and helped site visitors sign up for a user account, clarified the artifact maintenance and artifact update process, provided CDS

artifact authors access to a downloadable overview of the update review process, and encouraged members of the public to present at WG meetings by outlining the presentation process and requirements.

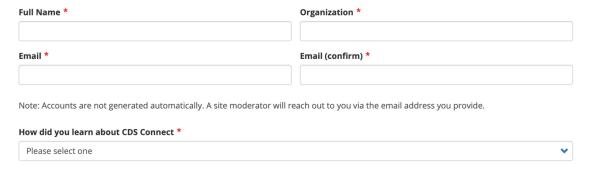
4.5.1 Improved user management

The team implemented a combined signup form to streamline requests for new CDS Connect accounts. User can now sign up for the Authoring Tool and the Repository permissions in a single step, rather than submitting two separate request forms. The new combined signup form also introduced an option for nontechnical end users of CDS Connect. Users can now request permissions as a Contributor (for those intending to create and post CDS artifacts) or a Community Member (for those who can log-in and view artifacts—and, in the future, subscribe to CDS artifacts notifications once subscriptions roll out. This leverages changes to the directory server to support the two levels of Repository user accounts. Prior to the directory server changes, this had to be manually managed by the team member creating new accounts based on the text of the request from the user.

An enhancement to request feedback on how the new user heard about CDS Connect was also added to the account signup form. The user can select a value from the dropdown list (e.g., colleague, conference/workshop, university class, etc) or choose "Other" and fill in a free text value. Developed to align with the NORC CDS Connect evaluation project, this enhancement gives insight into the reach and performance of the project, as well as helps quantify potential motivations for new account holders.

CDS Connect Account Sign-Up

Thank you for your interest in contributing to the clinical decision support community! A CDS Connect account will provide you with the ability to create, edit, publish and subscribe to clinical decision support artifacts.



Which permissions would you like associated with your CDS Connect account?

You may add or change permissions at a later date

Authoring Tool Login

Authoring Permissions are for software developers to create HL7 CQL-based CDS logic files using a friendly web interface and to test authored CDS logic against uploaded synthetic patient data.

Artifact Repository Login

- Contributor Permissions are for researchers and developers to create CDS artifacts at the multiple knowledge levels (L1-L4) and post them to the Repository for public review and use.
- Community Member Permissions are for anyone with an interest in clinical decision support to subscribe to Repository artifacts and receive notifications.

Note: A CDS Connect account is not a single sign on account. While your credentials are the same for the Artifact Repository and Authoring Tool, your login sessions are not shared between them. If you request both permission sets, be aware you may need to log in with your account

Figure 3. CDS Connect Account Signup Form with Options for Authoring Tool and Repository Permissions

4.5.2 General System Improvements

The team made many general system improvements to the Repository during Year 5.

The team updated the CDS Connect Repository API³ to adjust how related CDS artifacts are returned in GET requests. Previously, the list of related CDS artifacts only returned a list of strings. With the enhancement, a list of objects is returned with each object including the CDS artifact title, the artifact node ID number, and the CDS artifact Uniform Resource Locator (URL).

The repository team also added a set of tests to validate that the web form submissions generate email messages and that the email messages are delivered through the mail server. This is accomplished

³ The API was expanded and released as open source during Year 3.

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via a set of drush command-line plugins that submit each of the web forms with test data. Each of these drush plugins is then executed via a linux cron job that is executed once per week, on separate days for each test (cron is a linux utility that allows scheduling jobs to run on a given day of the week and at a particular time of day). This was an extension of the robustness improvements made in Year 4.

The team updated the Repository to ensure that security patches and bug fixes released for Drupal⁴ were applied in a timely manner. The Repository uses Drupal Version 9, which operates on a semiannual minor version release cycle. Because each minor release for Drupal receives security support for 1 year, it is important that the Repository stay current. As of the date of this report, the Repository is on the long-term support release for Drupal 9.

The cloud environments were updated to PHP 7.3 and then 7.4 during Year 5 to stay current with support. The move to PHP 8.x is planned for the near future,

as this has been enabled with the move to Drupal 9.x.

5. STANDARDS CONFORMANCE: AUTHORING TOOL

In Year 1 of the CDS Connect project, the team designed and built the CDS Authoring Tool, a user-friendly web application for creating standards-based CDS logic using HL7 CQL and HL7 FHIR. The team spent Years 2 through 4 improving the CDS Authoring Tool based on project requirements and user feedback. By the end of Year 4, the CDS Authoring Tool supported the following features:

- Logging in with a user account to manage a personal set of CDS logic artifacts.
- Authoring CDS logic using inclusion and exclusion criteria, sub-populations, and conditional recommendations.
- Integrating with the National Library of Medicine's VSAC to find and select value sets as well as to validate individual codes.

⁴ The Repository is based on Drupal as the underlying CMS. CDS Connect Maintenance and Update | Final Report

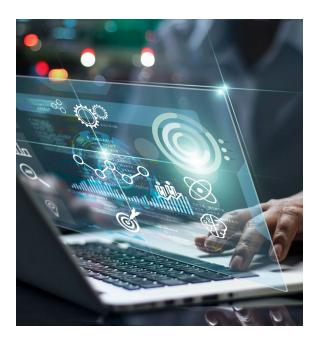
- Defining "base elements" that can be specified once and used multiple times throughout the CDS artifact.
- Importing externally authored CQL to support constructs not expressible in the CDS Authoring Tool.
- Specifying run-time parameters to allow implementers to change the behavior of CQL logic at run-time.
- Annotating CDS elements with humanreadable comments.
- **Testing** authored logic using synthetic data to verify its correctness.
- Exporting valid CQL using the FHIR Draft STU 2, FHIR STU 3, or FHIR Release 4 data models.

The CDS Authoring Tool is provided under an open-source Apache 2.0 license on GitHub and hosted in an AHRQ production environment. Going into Year 5, the CDS Authoring Tool had 367 registered users, with 609 registered users as of the writing of this report.

In Year 5, several organizations continued extension and reuse of the CDS Authoring Tool, including:

- An AHRQ grantee continued development of a prototype drug-drug interaction alerting system as an extension of the CDS Authoring Tool open-source code.
- Faculty at a medical school used the CDS Authoring Tool in their own CDS authoring platform along with several other open-source CDS tools.

In addition, several organizations expressed interest in using components of the CDS



Authoring Tool in future development efforts. The maintenance activities summarized in the previous section should enable future efforts such as these.

During Year 5, the team focused on aligning with current health IT standards, expanding available logical constructs for authoring, improving usability of the tool, and supporting easier maintenance and reuse of the open-source code.

5.1 CQL 1.5 Mixed Normative/ Trial Use

HL7 officially released CQL version 1.5 in May 2021. Unlike previous versions of CQL, this version contains "normative" content and was additionally approved by the American National Standards Institute (ANSI). Normative content is considered stable and should not introduce incompatible changes in future versions.

In Year 5, the CDS Connect team began an effort to align with the CQL 1.5 specification across its tools and CDS artifacts. To better

align with the CQL 1.5 specification in the CDS Authoring Tool, the team implemented three changes. First, the team updated the CQL-to-Expression Logical Model (ELM) translation service to translate all generated and uploaded CQL using the CQL 1.5 translator. Second, the team updated the CDS Authoring Tool's helper libraries to the most recent versions that are compliant with CQL 1.5. Last, the team upgraded the testing component's CQL execution framework library to its latest 2.x release.

As part of this effort, the team also implemented many new features, enhancements, and bug fixes in the CQL execution framework library. These updates include support for aggregate queries, runtime messages, various list operators, strict type casts, better handling of dates, and a variety of other CQL operators. For more details, see the CQL execution framework's 2.2.0 and 2.3.0 release notes.

5.2 Strength of Recommendation and Quality of Evidence

The CDS Authoring Tool aligns with FHIR Clinical Guidelines by allowing authors to specify FHIR Clinical Guidelines metadata related to the CDS library they are authoring. Support for specifying metadata defined in the CPGPublishableLibrary profile was added in Year 4. In Year 5, the CDS Authoring Tool added support for additionally specifying a CDS artifact's strength of recommendation and quality of evidence. These fields allow authors to choose from example values provided by the FHIR specification or to provide their own coded values. These values are exported in the library definition using the corresponding strengthofrecommendation and qualityofevidence extensions from the FHIR specification.



Figure 4. Specifying Strength of Recommendation and Quality of Evidence

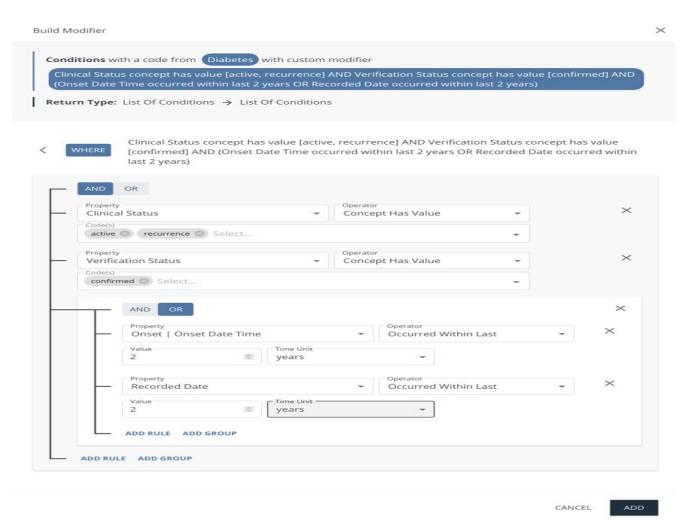


Figure 5. Specifying Query Criteria

5.3 Query Builder

The CDS Authoring Tool allows authors to filter or modify elements by choosing expression modifiers from a predefined list. For example, a list of conditions can be filtered using one or more of the following modifiers: Active, Active or Recurring, Confirmed, and Lookback. While these predefined modifiers represent the most common use cases, authors may want to filter using other criteria or a more specific combination of criteria.

In Year 5, the team added a capability that allows authors to build their own

modifiers by specifying detailed queries.

Using this capability, authors define criteria by selecting resource properties, operators, and values. For example, an author can choose a code-based property and indicate a set of codes it should match against. As another example, an author could choose a quantity-based property and indicate a range it should fit within. Authors combine multiple criteria in groups to build more complex logical criteria. In Figure 5, an author has defined a query representing the following:

Conditions indicating diabetes WHERE

- clinical status is active or recurrence AND
- verification status is confirmed AND
 - onset date/time is within the last2 years OR
 - recorded date is within the last2 years

This flexible approach to specifying filter criteria allows authors to represent their requirements while reducing the number of predefined expression modifiers that the CDS Authoring Tool needs to provide.

5.4 External CQL Functions

The CDS Authoring Tool now allows authors to use functions from external CQL libraries in their own CDS artifacts. Authors can invoke functions directly by supplying values for required arguments or they can invoke them as part of the familiar "expression-modifier" workflow. In both cases, all arguments to the function must either be supported by a built-in form editor (e.g., strings, numbers, dates) or match the return type of a defined parameter, base element, or other external CQL definition.

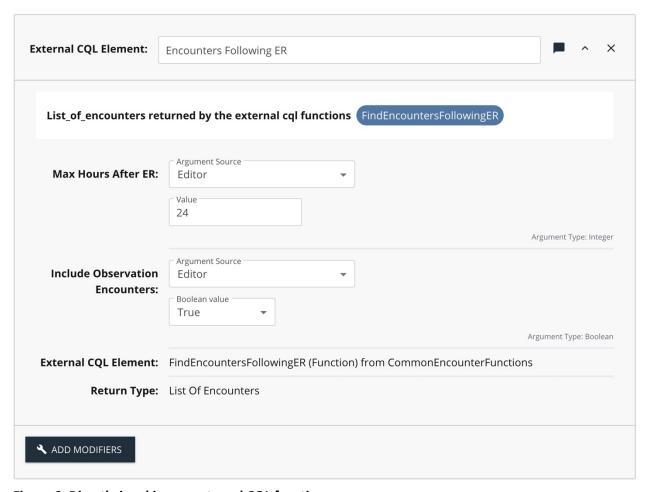


Figure 6. Directly invoking an external CQL function

```
define function CalculateScore("Vitals" List<Observation>, "Use Experimental Algorithm" Boolean):
    if "Use Experimental Algorithm" then
        // experimental agorithm goes here (removed for brevity)
    else
        // standard algorithm goes here (removed for brevity
```

Figure 7. External function taking a list of Observations as the first argument

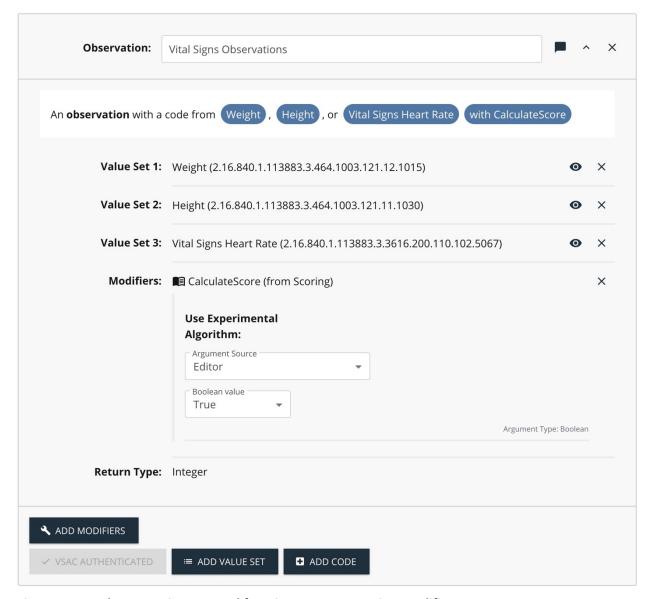


Figure 8. CDS element using external function as an expression modifier

When authors build elements, if the current return type of the element matches the first argument of any external CQL function, that function will also be available as an expression modifier. In the case above, the returned list of vital signs observations is used as the first argument to the CalculateScore function, and the second argument value is provided by the author via an editor form.

5.5 Additional Resources and Modifiers

The CDS Authoring Tool allows authors to choose from a list of popular FHIR resources when creating an element. In Year 5, the team added support for the ServiceRequest resource with the following expression modifiers: Look Back, Count, Exists, Is (Not) Null, Active or Completed, Active, and Completed. Since ServiceRequest is only available in FHIR R4, CDS artifacts that are locked to earlier versions of FHIR

cannot use it. In addition, when a CDS artifact uses the ServiceRequest resource, it will be locked into the FHIR R4 data model.

In addition, the team added support for several other expression modifiers on other resources, including the "First" expression modifier for Observations, Conditions, Procedures, and Immunizations, as well as the "Average Observation Value" modifier for Observations.

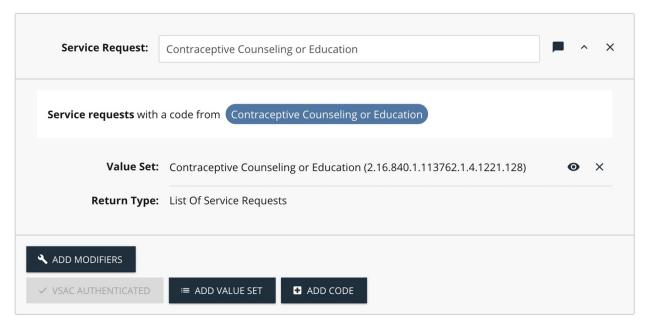


Figure 9. ServiceRequest element

5.6 Recommendation Links

The CDS Authoring Tool primarily supports text recommendations, including additional text for the rationale. In Year 5, the team added support for optionally including one or more links associated with each recommendation. For each link, the author must provide a label, a type ("absolute" or "smart"), and a URL. This allows authors

to link recommendations to sources, additional information, Substitutable Medical Applications, Reusable Technologies (SMART) applications, and/or any other relevant document. This approach aligns with the CDS Hooks specification's card links attribute, allowing for easier integration with CDS Hooks services.

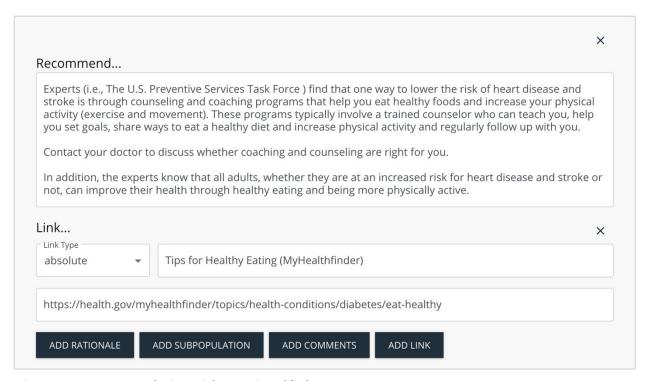


Figure 10. Recommendation with associated links

5.7 UMLS API Key

The CDS Authoring Tool integrates with the National Library of Medicine's VSAC to provide terminology services for searching and selecting value sets, as well as for testing CDS artifacts that use value sets. In 2020, VSAC updated their API to require a UMLS API key for authentication. As a result, the CDS Connect team updated the CDS

Authoring Tool to prompt users for their UMLS API key when performing actions that require access to the VSAC. This enhancement also applied to the Open-Source Tools (6.1.5), CQL Testing Framework and Enhancements (6.2.3), and Pain Management Summary Application Enhancements (6.3.3).

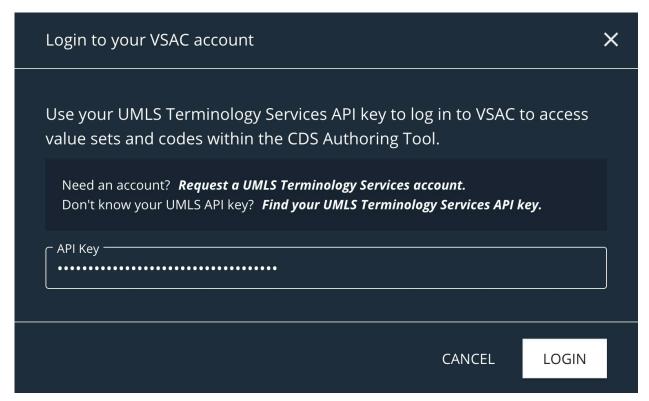


Figure 11. Entering a UMLS API key to search for value sets

5.8 Usability

The team also focused on improving usability of the CDS Authoring Tool. Usability enhancements were based on feedback from users and usability experts inside and outside the team. A review of a representative sampling of usability enhancements implemented in Year 5 shows the many improvements in the CDS Authoring Tool experience. For example, users can:

- Go directly to the CDS artifact list upon successful authentication.
- Sort their CDS artifact list based on name, version, date last changed, and date created.
- Duplicate an existing CDS artifact to get a head start on editing a new CDS artifact.
- View a high-level overview of their CDS artifact's basic metadata and logic.

- Quickly see what components of a CDS artifact are populated and/or have errors.
- Maintain editing context via a "sticky" tab row that is always visible.
- Select value sets with or without previewing their contents.
- Remove expression modifiers from the middle of an expression modifier sequence.
- Navigate between parameter definitions and their uses in the CDS artifact.
- Understand error messages more clearly due to improved text and suggestions.

In addition, many components of the CDS Authoring Tool received a visual refresh as the team adopted modern component libraries such as Material-UI, a React framework that follows material design principles.

| ARTIFACT NAME | VERSION | LAST CHANGED ↑ | DATE CREATED | | |
|--|---------|-----------------------|------------------|---|---|
| Statin Use for the Primary Prevention of CVD in Adults | 0.1.0 | about 23 hours ago | 4 months ago | j | ī |
| Healthful Diet and Physical Activity Demo | 0.0.1 | 28 days ago | over 1 year ago | ľ | î |
| Pain Management Summary | 1.0.0 | 28 days ago | over 2 years ago | 1 | î |
| Diabetes Foot Exam | 0.0.1 | about 1 year ago | about 1 year ago | , | Ē |

Figure 12. CDS Artifact table with new sorting and duplication features

5.9 Maintainability

Over the past 5 years, open-source technologies for building dynamic web applications have continued to improve. During that time, requirements for the CDS Authoring Tool have become clearer and the team has learned much. In Year 5, the team focused on applying these new technologies, lessons learned, and best practices to the CDS Authoring Tool code base to improve its quality, efficiency, maintainability, and ease of reuse. This significant effort included activities such as:

- Adding, removing, and updating dependency libraries as appropriate.
- Switching homegrown components to use Material-UI.
- Leveraging React Hooks to simplify component logic, lifecycles, and state management.

- Modularizing components for reuse across the application and in other applications.
- Defining styles local to the components where they are used.
- Application of consistent coding practices.

As a result, teams working on the CDS Authoring Tool can onboard new developers more quickly, maintain the code more easily, and implement new features more efficiently. In addition, external teams can more easily extend the CDS Authoring Tool or reuse components from the CDS Authoring Tool in their own applications.





6. STANDARDS CONFORMANCE: OPEN-SOURCE TOOLS

The CDS Connect project has developed other open-source tools over previous years. These include CQL Services, the CQL Testing Framework, and the Pain Management Summary Application.

6.1 CQL Services and Enhancements

CQL Services is an open-source application that enables users to expose CQL-authored logic over custom and standards-based web services. In Year 5, the team continued to provide enhancements and bug fixes to CQL Services in alignment with overall project goals.



Figure 13. Example CQL Services Response in the CDS Hooks Sandbox

6.1.1 FHIR 4.0.1

Prior to Year 5, CQL Services supported the FHIR 1.0.2, 3.0.0, and 4.0.0 data models. In Year 5, the CDS Connect team updated this support to also include the FHIR 4.0.1 data model. As a result, CQL libraries authored using the FHIR 4.0.1 data model can now be integrated with and exposed via CQL Services. This enhancement also applied to CQL Testing Framework and Enhancements (6.2.1), and Pain Management Summary Application Enhancements (6.3.1).

6.1.2 CQL 1.4/1.5

CQL Services uses an open-source JavaScript CQL execution engine to process CQL libraries. Prior to Year 5, this engine supported CQL 1.3. In Year 5, the CDS Connect team updated the CQL execution engine to better support CQL 1.4 and CQL 1.5. As a result, CQL Services provides improved support for CQL libraries that use features that are new or changed in CQL 1.4 and CQL 1.5. This enhancement also applied to the CQL Testing Framework and Enhancements (6.2.3).

6.1.3 FHIR Server Callbacks

Prior to Year 5, CQL Services required all data to be provided as part of the CDS request (in the "prefetch" parameter). Requests that did not include all the required data were rejected. In Year 5, the CDS Connect team implemented support for querying back to a FHIR server when the required data are not provided as part of the CDS request. This improvement addressed a significant gap in CQL Services'

implementation of CDS Hooks and allowed it to interoperate with vendors that do not provide prefetch data as part of the CDS request.

6.1.4 Configurable Prefetch Templates

The CDS Hooks specification defines a mechanism called "prefetch templates" that allows services to specify data that can be optionally provided with service requests. By default, CQL Services generates simple prefetch templates by analyzing the underlying CQL libraries that the service uses. In Year 5, the team provided support for user-configurable prefetch templates so that integrators can override the generated prefetch template with their own.

6.1.5 UMLS API Key

As discussed for the CDS Authoring Tool (5.7), this enhancement also applied to open-source tools.

6.2 CQL Testing Framework and Enhancements

The CQL Testing Framework is an open-source library that allows developers to create and execute tests cases for CQL libraries. Unlike the testing feature in the CDS Authoring Tool, the CQL Testing Framework can work with any CQL (wherever it was developed) and can test actual against expected results. In Year 5, the team continued to provide enhancements and bug fixes to the CQL Testing Framework.

```
pain-management-summary-cql $ npm test
> pain-management-summary-cql@1.0.0 test /Users/cmoesel/dev/cds-connect/pain-management-summary-cql
> mocha --reporter spec --recursive
CQLT Config: /Users/cmoesel/dev/cds-connect/pain-management-summary-cql/test/pms-cqlt.yaml
  Factors_to_Consider_in_Managing_Chronic_Pain_v1.0.0
    ✓ Aged 17 years or younger
    ✓ Aged 65 years or older

✓ Has Benzodiazepine Order (Diazepam)

✓ Has a Resolved Condition Likely to Indicate Chronic Pain (Fibromyalgis)

✓ Has Condition Likely to Indicate Chronic Pain (Fibromyalgis)

✓ Has High Risk Encounter Diagnoses for Opioid Therapy (Suicide attempt)

✓ Has Recent MME Calculation

✓ Has Non-Opioid Order (Aspirin)

✓ Has Numeric Pain Intensity Assessment (FACES)

✓ Has Opioid Order (Oxycodone)

✓ Has Pain Management Risk Screening (PHQ-9)

✓ Has PEG Assessment

✓ Has Multiple Urine Drug Screens (Opiates [Presence])
  13 passing (132ms)
```

Figure 14. Using the CQL Testing Framework to Test a CQL Library

6.2.1 FHIR 4.0.1

The CQL Testing Framework can now test CQL libraries authored using the FHIR 4.0.1 data model. In addition, the CQL Testing Framework continues to support testing CQL libraries authored using the FHIR 4.0.0, FHIR 3.0.0, and FHIR 1.0.2 data models.

6.2.2 CQL 1.4/1.5

As discussed for the CQL Services and Enhancements (6.1.2), this enhancement also applied to CQL Testing Framework and Enhancements.

6.2.3 UMLS API Key

As discussed for the CDS Authoring Tool (5.7), this enhancement also applied to CQL Testing Framework and Enhancements.

6.3 Pain Management Summary Application and Enhancements

The Pain Management Summary
Application is a SMART on FHIR application
that allows clinicians and patients to view
all individual patient data that might be
relevant to managing that patient's pain.
The Pain Management Summary application
was developed and piloted in Year 2 of CDS
Connect. In Year 5, the team updated
the Pain Management Summary
Application to maintain alignment with
the most recent standards and practices.

Existing reuses of the Pain Management Summary application continued in Year 5. In two cases, organizations have adopted and extended the Pain Management Summary application to provide additional



Figure 15. The Pain Management Summary Application

pain-related data, including data from prescription drug monitoring programs. In the third case, an organization reused the overall structure of the Pain Management Summary application but replaced all the pain-related content with content pertaining to COVID-19.

6.3.1 FHIR 4.0.1

In Year 4, the team developed a FHIR R4 representation of the Pain Management Summary's underlying CQL logic using the FHIR 4.0.0 data model. In Year 5, the team updated the CQL logic to use the FHIR 4.0.1 data model. This did not substantially change the CQL, as FHIR 4.0.1 is a technical correction update to FHIR 4.0.0. The team also updated the application itself to use the FHIR 4.0.1 data model provider when executing the CQL. To maintain compatibility with the widest variety of health IT products, the team retained support for FHIR Draft Standard for Trial Use (DSTU) 2. When the latest version of the Pain Management Summary Application launches, it dynamically detects the version of FHIR in use and acts accordingly.

6.3.2 CQL Logic

In Year 5, the team updated the Pain Management Summary Application's underlying CQL logic to currently follow recommendations, practices, and capabilities of the CQL specification. This primarily consisted of two changes. First, all value set references were updated to use canonical URLs rather than Object Identifiers (OID) to identify value sets. Second, "concept" definitions that merely reflected an existing "code" definition were removed in favor of the single "code" definition. The Pain Management Summary Application uses a set of synthetic patients for testing the application. Over the years, these test patients have needed to be updated because their data have "timed out" of the lookback windows used in the CQL logic. In Year 5, the team developed a script that can be run to easily update all synthetic patients so that their data remain in all intended lookback periods.

6.3.3 UMLS API Key

As discussed for the CDS Authoring Tool (5.7), this enhancement also applied to the Pain Management Summary Application and Enhancements.



7. STANDARDS CONFORMANCE: CDS ARTIFACTS

The team reviewed and updated all MITREauthored CDS artifacts developed within the CDS Connect project (as described in <u>Table 1</u>). The team's criteria for considering updates included consideration of new relevant professional guideline or research evidence, value sets, updated FHIR and CQL standards, documentation, and metadata, as described in the FAQ section called <u>How do I maintain my contributed CDS artifacts?</u>

Table 1. Annual Review and Update of CDS Connect Project Team Authored CDS Artifacts

| CDS Artifacts⁵ | Evidence Updates | Value Set updates | Logic Updates | Metadata Updates |
|--|---------------------|-------------------|------------------|------------------|
| Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part One, Screening | No | Yes | Yes | Yes |
| Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part Two, Counseling | No | Yes | Yes | Yes |
| Aspirin Therapy for Primary Prevention of CVD and Colorectal Cancer | No | N/A | No | Yes |
| CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10- Year ASCVD Risk | No | N/A | Yes | Yes |
| CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Shared Decision Making | No | N/A | No | Yes |
| CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Updated 10- Year ASCVD Risk | No | N/A | No | Yes |
| Factors to Consider in Managing Chronic Pain: A Pain Management Summary | Yes | Yes | Yes | Yes |
| Healthful Diet and Physical Activity for CVD Prevention in Adults With Cardiovascular Risk Factors | Yes | Yes | Yes | Yes |
| Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) eCQM | Yes | Yes | Yes | Yes |
| Statin Use for the Primary Prevention of CVD in Adults: Clinician-Facing CDS Intervention | No | Yes | Yes | Yes |
| Statin Use for the Primary Prevention of CVD in Adults: Patient-Facing CDS Intervention | No | Yes | Yes | Yes |

⁻

^{5 &}lt;u>Occupational Factors Impacting Diabetes</u> is under consideration for update or retirement in coordination with the National Institute for Occupational Safety and Health.

The clinician and informaticist roles were new to the team this year; in collaboration with other team members, they created a detailed step-by-step process for updating each component of a CDS artifact. The team further created a one-page summary infographic of the process. Finally, they created and updated the "How do I maintain my contributed CDS artifact?" FAQ section of the AHRQ CDS Connect website.

The clinical lead created and delivered a presentation to the WG on May 20, 2021, describing the draft update process. Members of the WG provided pertinent and helpful suggestions, which improved the update process.

All CDS Connect project CDS artifacts with CQL representations were updated to use the FHIR 4.0.1 data model and CQL 1.5. In addition, all IGs have received an editorial review to improve clarity of writing and have been made 508 compliant.

As in earlier project years, the team worked with the CDS community, including the WG, during Year 5 to review and update other CDS artifacts contributed to the Repository outside of the team. This effort is a major accomplishment to maintaining trust in CDS Connect. Upon request, the team worked with CDS artifact authors to review and update their CDS artifacts (i.e., Clostridioides Difficile (C. diff) Infection (CDI) Treatment Pathway and Refugee Health Decision Support), including a review of their evidence, metadata, value sets, and documentation. Related to this implementation of CDS Connect Governance, the team is preparing

an article for invited submission to a peerreviewed journal.

The team also worked with contributors providing new CDS artifacts to the Repository (i.e., NIOSH, CDC, HLN Consulting, and TISTA Science and Technology Corporation). Contributors included other Federal agencies, existing contributors, and individuals within medical systems. Activities included providing informational meetings to those asking to learn more about the contribution process, creating accounts and advising them on how to use the Repository, and reviewing submitted material ahead of publishing it to the CDS Connect Repository.

Finally, the Project and Authoring Tool Leads participated monthly in the Value Set work group to provide feedback on the use of the Value Set Authority Center, as well as provide a use case for how CDS uses the value sets.

7.1 Work Group

The WG serves a critical function by providing diverse subject matter expertise to aid in the prioritization of CDS Connect development activities. The WG has engaged throughout key project phases, from consideration of high-level desired outcomes for CDS Connect to selection of optimal approaches for maintaining and updating CDS Connect. In Year 5, the team worked with the WG moderator to maintain the CDS Connect WG, while increasing the diversity of participation and presentation, including—but not limited to—facilitating monthly virtual meetings, developing and inviting content, summarizing meetings through publicly available notes

and presentation materials, and responding to questions from new and existing members.

The team works with the WG's 141-plus members to promote engagement from the diverse members, whose expertise ranges from clinicians to coders. The team hosted six "lessons learned" presentations in Year 5. The team maintained the prior year practice of conducting a shorter, 60-minute meeting, sharing the draft slide deck in advance, and highlighting specific feedback needed from presenters. During the meetings, the team focused on specific discussion questions with clear objectives and used the chat feature to invite greater participation. Attendance and participation increased following these changes. It will be important to watch trends over time and solicit feedback on the changes from WG members.

The CDS Connect WG met 11 times during the reporting period (September 2020–August 2021). The WG meeting was canceled in December, based on members' limited availability and preference. Meetings averaged 45 WG members a month, and overall attendance ranged from 39 to 64 attendees. Six guest speakers presented on lessons learned using CDS Connect CDS artifacts:

- Building an Accelerated and Participatory CDS using Blockchain Technologies.
- b.well Connected Health U.S.
 Preventive Services Task Force
 (USPSTF) Recommendations Pilot.
- Supporting Implementers of Shareable CDS with IGs.
- Person-First Safe Living in a Pandemic.
- Using CDS to Reduce Harm from Drug-Drug Interactions: Case Study of Warfarin and Non-Steroidal Anti-Inflammatory Drugs.
- CDS for Asthma Management Guidelines.

Additionally, The AHRQ Center for Evidence and Practice Improvement Evidence Discovery and Retrieval team presented on their clinical evidence repository effort and shared a request for a pilot partner.

The MITRE team presented four topics to gather feedback and promote discussion among WG members. These topics included the stewardship and versioning of CDS artifacts, Project Year 5 priorities, patient partnering and related site changes, and the CDS artifact review and update process.



8. OUTREACH

During Year 5, the team's outreach efforts concentrated increasing the use of CDS Connect tools by the CDS community. Activities included:

- **Demonstrating** CDS Connect tools and functionalities.
- Facilitating and participating in meetings between AHRQ and stakeholder groups (e.g., potential sustainer organizations, Federal partners, and grantees).
- Tracking stakeholder recommendations for consideration in future sprints.
- Presenting at national research or developer conferences.
- Participating in appropriate standards WG meetings (e.g., HL7 and VSAC).

Building awareness and use of CDS
 Connect using varied platforms
 (e.g., email notifications, peer-reviewed publication).

In-person conference attendance continued to be impacted by the COVID-19 pandemic, so the team continued to seek virtual and varied media for outreach opportunities. This year, the team sought opportunities smaller in scale, but with opportunity for greater depth. For example, the team convened a two-part series on patient partnering to discuss with the WG that resulted in the development of a time-limited Patient Partnering Panel.

Ultimately, the team's alternative outreach plan succeeded in meeting project requirements and providing continued engagement with the CDS community during the continuation of an unprecedented time. The alternative plan continued to allow greater resources for development efforts and avoid delays in development efforts that often coincide with team travel.

8.1 CDS Community

The team regularly engages with CDS community stakeholders beyond the CDS Connect WG. These engagements include existing contributors (e.g., HLN Consulting, LLC); Federal partners (CMS [including Value Set WG], CDC, and National Institute of Occupational Safety and Health); and other CDS meetings (e.g., holding an informational CDS artifact contribution meeting with Northwell Health). The team also participated in Connecting Disparate Systems: Reducing Occurrences of Child Abuse and Neglect by Connecting Emergency Departments (EDs) and Child Protective Services (CPS)," 3rd Annual UPMC Children's Hospital of Pittsburgh Child Abuse Clinical Decision Support Conference, October 21-22, 2020, with CDS Connect referenced as an example of a standards-based approach to developing CDS. The team also continued to collaborate with other AHRQ projects, such as the AHRQ evidence-based Care Transformation Support (ACTS) project to gather requirements for future potential improvements to the CDS Authoring Tool.

The team continued sending regular updates by email to WG members and others who had signed up through the CDS Connect website. The email updates summarized recent development efforts reported during the WG meeting and were intended to help drive traffic to the CDS Connect site. The team sent two email updates this project year (emails are sent only when there is enough content to warrant a send to avoid burdening recipients), with the December update going to 673 recipients and the May update going to 480 recipients. The decrease in May's recipients is attributed to removing bounceback email addresses.

To provide a patient perspective, Danny van Leeuwen (HealthHats) continued to serve as a patient/caregiver activist and advocate, working closely with CDS Connect. He participated regularly in the CDS Connect WG and provided critical input on public-facing outputs (e.g., updates to graphics on the CDS Connect site to better reflect the role of patients and caregivers in CDS development). With the focus of alternative outreach on smaller, in-depth engagements, the team created a time-limited Patient Partnering Panel made up of interested members from the CDS community, including six WG members. The panel met four times over the summer to discuss, define, and shape resources to help CDS developers and implementers partner with patients/ caregivers during the development and implementation of CDS. The panel aimed to bring attention to the need for practical guidance, even standards, for integrating the patient/caregiver voice into CDS.

Facilitated by the patient advocate and structured with a collaborative, asynchronous working space (i.e., MURAL), the sessions helped clarify that the overall CDS development community is only beginning to incorporate patient and caregiver partnering into their efforts. Participants were eager for resources and examples from others. The final session concluded with a discussion of lessons learned and a review of the draft content of three summary handouts.



8.2 Conferences

The team attended several conferences or events in Year 5, with the goal of identifying current trends and issues related to patient-centered CDS, gauging attendees' level of awareness and use of CDS Connect, and promoting the use of CDS Connect tools.

8.2.1 2020 University of Washington FHIR Conference

The University of Washington (UW) FHIR Conference invites people from inside and outside of the UW community to learn more about FHIR and its related standards. The 2020 UW FHIR Conference was held in September 2020 as a virtual event. UW conference organizers invited the CDS Connect team to participate in the panel, "FHIR in Public Health and Clinical Decision Support for Opioids Harm Reduction." As part of the panel, a member of the CDS

Connect team presented an overview of the Pain Management Summary SMART on FHIR application. The overview covered the development of the CQL logic and web application, clinical pilot testing, and lessons learned. In addition, a team from UW presented an extension of the Pain Management Summary application that integrates the Washington State Prescription Drug Monitoring Database.

8.2.2 American Medical Informatics Association 2020 Annual Symposium

The American Medical Informatics Association (AMIA) Annual Symposium provides a venue for clinical informatics researchers and implementers to share insights with one another.

The <u>AMIA 2020 Annual Symposium</u> was held in November 2020 as a virtual event. Three members of the CDS Connect Team attended the conference, one of whom

also co-led a 3-hour CDS workshop. The team identified a few items relevant to CDS Connect, including the need for outreach to get the CDS Connect tools into the hands of frontline works (particularly in the time of the COVID-19 pandemic, when evidence is rapidly generated and needs to be incorporated into practice). The team also heard from the CDS community that FHIR R4 is being widely adopted with caution (as is FHIR generally) to ensure versions are not changed so rapidly that it is challenging to maintain adoption. Lastly, the team heard the need for standards, monitoring of bias, and use of human factors and cognitive engineering to ensure CDS is relevant to patients and caregivers.

"The New Digital Age of Clinical Decision Support Tools: Open-source and Interoperable Approaches for Health Systems" workshop was proposed, planned, and performed by several individuals from academia, government, and industry. To introduce the workshop, a member of the CDS Connect team provided an overview of current CDS standards, technologies, and tools. Participants in the workshop then worked with a virtual machine image, provided by University of Colorado, to create and test an example CDS artifact. These participants used two CDS Connect tools: the CDS Authoring Tool and CQL Services. More than 50 people participated in the workshop, many of whom reported that they found the workshop useful and informative.

8.2.3 American Medical Informatics Association Clinical Informatics Conference 2021

The AMIA Clinical Informatics Conference provides a focused space for informaticists to delve into relevant research topics, including a focus on CDS. The virtual conference was held in May 2021, with two team members in attendance, one of whom co-led a panel on patient partnering. The team identified themes in CDS development and implementation, trust, and patient engagement. Key considerations include being ever mindful of the end user of the CDS and creating transparency around the CDS, particularly when artificial intelligence or machine learning models are used.

The panel "Nothing for Me or About Me, Without Me: Co-Design of Clinical Decision Support" was proposed, planned, and presented through a collaborative effort across the government and industry. The AHRQ lead for CDS Connect facilitated the panel, while the MITRE lead and patient/ caregiver activists shared their perspectives on including patients and caregivers in CDS design. More than 30 attendees participated in the panel and engaged through the conference platform.

8.2.4 HL7 FHIR Connectathon 27

The HL7 FHIR Connectation provides opportunities for stakeholders in the FHIR community to collaboratively develop, test, and discuss FHIR-based specifications and implementations.

HL7 FHIR Connectathon 27 was held in May 2021 as a virtual event with over 40 different tracks. Two members of the CDS Connect team actively participated in the CDS Hooks track, while a third member of the team visited several of the other offered tracks.

The CDS Connect team joined the Connectathon to test the CQL Services prototype tool against vendor implementations of the CDS Hooks specification. Since the focus was on the CQL Services tool, rather than any specific CDS artifact, the team configured the tool with an example CQL library that demonstrated only basic CQL capabilities. Over the course of the Connectathon, the team demonstrated

successful interoperability with all three CDS Hooks "clients" that participated in the CDS Hooks track: Cerner, CorroHealth, and Epic. Successful testing with Epic required minor modifications to the CQL Services source code, as well as custom configuration of the "prefetch template."

In addition to testing, the CDS Connect team provided a 30-minute overview and demonstration of CQL Services to track participants who had indicated interest in learning more about the tool. During this session, participants also discussed the various challenges to frameworks such as CQL Services, as well as potential approaches to addressing those challenges.

8.3 CDS Connect Site and GitHub Metrics

Year 5 of CDS Connect marked the first year in the project of having regular site metrics. On average, the CDS Connect landing page received 370 unique views each month, with the Repository being the next most

visited page. CDS artifacts are the most downloaded each month (approximately 21 downloads per month for that month's top two CDS artifacts).

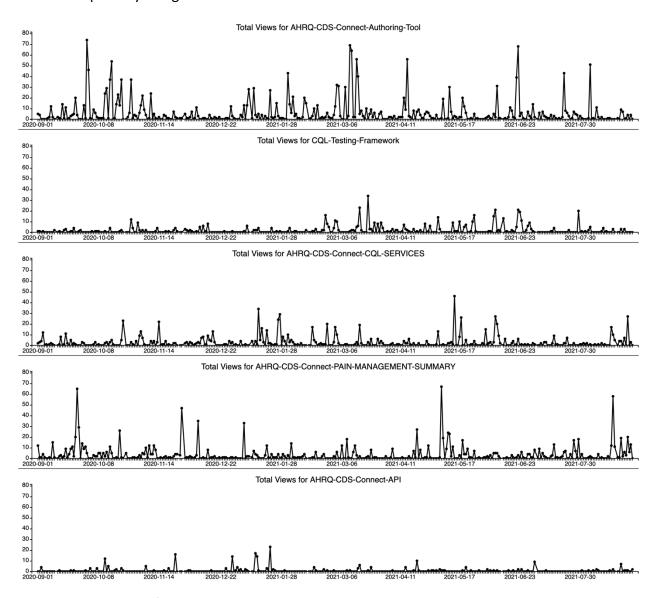


Figure 16. Total Views for AHRQ-CDS GitHub Repositories

CDS Connect shares open source code on GitHub. Figure 16 and Figure 17 display page views and clones, respectively, beginning September 2020 until August 2021. On GitHub, a "clone" represents

when a user has downloaded the opensource code to their system for local use and modification.

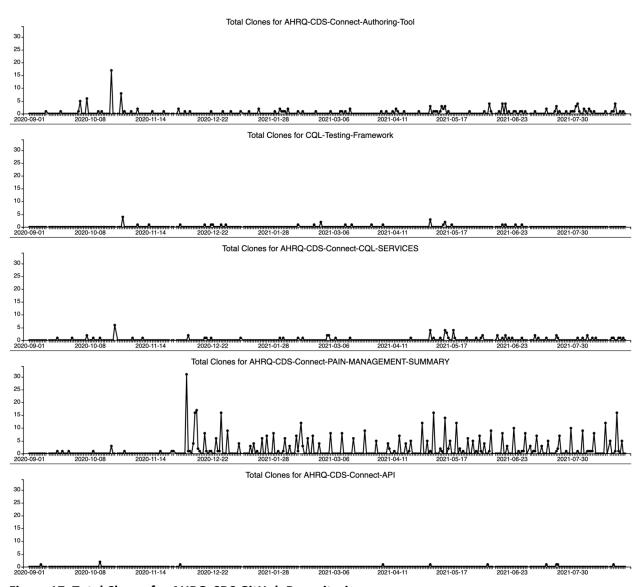


Figure 17. Total Clones for AHRQ-CDS GitHub Repositories



9. LESSONS LEARNED AND RECOMMENDATIONS

The following observations gleaned through the team's Year 5 activities may be useful for CDS projects and the broader CDS community.

- 1. Enforcing Standards Compliance:
 - Enhance CDS artifacts with the latest standards, as available. Keeping pace with the latest versions to promote interoperability of the CDS artifacts is sought after by the CDS community and prudent based on feedback during outreach. This year, all MITRE-authored CDS artifacts for this project were updated to FHIR R4 and CQL 1.5. The team also created updated guidance to promote the review and update of CDS artifacts contributed to the Repository by the CDS community.
- Recommendation: As standards continue to evolve and community adoption continues to increase, the CDS Connect team should strive to better support existing standards and add support for emerging standards. This may include activities such as implementing additional features of CQL 1.5, enhancing FHIR Clinical Guidelines integration, and tracking the upcoming FHIR Release 4B and Release 5 standards.
- Take advantage of opportunities
 to test CDS tools against real-world
 implementations. While standards
 are intended to promote interoperability,
 they are not a guarantee of
 interoperability. Vendors often
 interpret standards in different ways
 and often do not support every aspect
 of each standard. The only way to
 ensure interoperability is to test it.

This year, the team participated in the HL7 FHIR Connectathon 27 to test the CQL Services prototype tool against real-world implementations. As a result, the team learned valuable lessons about specific vendor implementations and how best to accommodate differences between vendors.

Recommendation: The team will prioritize functional outreach engagements like the HL7 FHIR Connectathon 27 that have the potential for immediate impact on the use of CDS Connect's tools by the community.

Monitor for equity in CDS development and implementation.

As the team continued to monitor the role the Food and Drug Administration will have in the regulation of certain types of CDS, this last year has also brought needed scrutiny to the potential for bias in CDS that may hinder efforts to achieve equity in healthcare. As CDS is meant to close the gap between evidence-based research findings and healthcare practice, it is necessary to rapidly evolve the development and implementation of CDS to keep pace with societal needs.

Recommendation: The team will continue to monitor the discussions of regulation and bias as it relates to CDS. Based on continued research, the team will consider approaches to share and integrate the findings into CDS Connect, which may include presentation and discussion with the WG, development of resources for the CDS

Connect site, or modification to CDS artifact metadata in the Repository.

2. Expanding Use:

• Gather regular use statistics for CDS Connect. As CDS Connect matures, it is paramount to document and understand its use in the CDS community. Having started the process of regularly gathering use statistics for the open-source testing and implementation tools in Year 4, this year we began regularly gathering use statistics for site visits and downloads on the CDS Connect site itself. This information has allowed the team to better understand the impact of outreach activities and consider priorities for enhancement.

Recommendation: CDS Connect is a maturing platform that will benefit from further enhancements and outreach activities that will have a lasting impact on overall use. For example, small-scale outreach events saw greater traffic to account creation than larger venues. It will be prudent to formally draw out the potential journey from enhancement or event to desired use. Considering direct access to generate these meaningful performance metrics on demand would help draw insights of value to future transition activities.

Responsive to the CDS community.
 This year, the CDS Connect WG members were more focused on prioritizing enhancements for CDS artifacts, as opposed to other elements of CDS Connect. The team recognized this need and looked to identify ad hoc activities to further enhance

engagement with the community and use of CDS Connect, including focused outreach activities and published pieces.

Recommendation: The team will continue to work closely with the CDS community to help guide the direction of CDS Connect, with exploration of how the use of CDS Connect resources is achieving impact, as well as drawing connections across industry to identify where challenges remain in the development and implementation of CDS. For example, CDS artifact development encompasses a wide variety of use cases and requirements. The team should consider approaches to improving the CDS Authoring Tool's ability to support these use cases and requirements. This may include implementing recommendations from other projects, such as the AHRQ evidence-based Care Transformation Support (ACTS) initiative.

3. Increasing Trust:

 Transparency remains critical to the success of CDS. The team continues to hear from the CDS community, via the WG and outreach, that transparency in the development of CDS is critical, particularly as artificial intelligence models continue to be developed for use in CDS applications. The team pursued efforts around patient partnering to further promote transparency in CDS development and implementation. Currently, the team is exploring how patient involvement can occur and be reflected after the fact, with the intent to promote transparency in how CDS is created and described.

Recommendation: With last year's efforts to create easily accessed information about CDS Connect (e.g., lessons learned series, video, and podcast), this year the team went deeper and focused on the challenge of integrating the end user of the CDS into the original development of that CDS. Next year, CDS Connect may benefit from having these efforts linked and presented as an informational session to various groups (e.g., evidence-based practice centers or AHRQ grantees).

Overall, lessons learned applicable to the broader CDS community include themes of use and standards of CDS artifacts and trust. The CDS community greatly supports the selection of priorities when there are more options available than resources to perform them all. The team actively seeks enhancements to CDS Connect that will promote implementation and use and pursues proactive efforts toward these ends. For example, efforts are underway to continue identifying and defining standards for patient partnering in the development and implementation of CDS, which can have a profound impact on the use of the CDS, as well as how it is perceived by the broader community, where equity and transparency are sought. The CDS community remains in need of standards and guidance on the development and use of standards in lesser applied domains like patient partnering. Equally important is that the standards are being applied with trust in mind and in a manner that will support the continued use of the CDS.

ACRONYMS

Term Definition

ACTS AHRQ evidence-based Care Transformation Support

AHRQ Agency for Healthcare Research and Quality

AMIA American Medical Informatics Association

API Application Programming Interface

ASCVD Atherosclerotic Cardiovascular Disease

CDC Centers for Disease Control and Prevention

CDS Clinical Decision Support

CMS Centers for Medicare & Medicaid Services

CPG Clinical Practice Guidelines

CPG-on-FHIR Representation of CPG recommendations in FHIR

CQL Clinical Quality Language
CVD Cardiovascular Disease

DSTU Draft Standard for Trial Use

eCQM Electronic Clinical Quality Measure

ELM Expression Logical Model

FFRDC Federally Funded Research and Development Center

FHIR® Fast Healthcare Interoperability Resources

HL7[®] Health Level Seven

IG Implementation Guide
IT Information Technology

OID Object Identifier

PCCDS-LN Patient-Centered Clinical Decision Support Learning Network

PCOR Patient-Centered Outcomes Research

R4 Release 4

SMART Substitutable Medical Applications, Reusable Technologies (a FHIR application)

STU Standard for Trial Use

URL Uniform Resource Locator

UMLS Unified Medical Language System

VSAC Value Set Authority Center

WG Work Group